TITLE: Clinical Illnesses and Laboratory abnorma*l*ities in Healthy HIV Vaccine Trial Participants in Uganda; Implication for future trials in resource limited settings.

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Background
Early phases of preventive vaccine trials typically enroll healthy participants. However, trials in developing countries are conducted in an environment of multiple infectious diseases. This can result in unexpected demands on trial resources. This abstract describes events that were un-related to vaccine, which occurred during a phase I/II trial conducted in 144 HIV uninfected healthy adults in Kampala.
Methodology
Participants' health status was established during screening. Protocol specific clinical and laboratory evaluations were done and documented as scheduled throughout the study period (13months) and as necessary when participants were ill. Relatedness of each event to study product was determined and documented. Data was analyzed using frequencies and proportions.
Results
There were 426 events of which 355 (83%) were clinical illnesses while 71(17%) were laboratory abnormalities. 129 of the 144(90%) participants presented with a least one event. Most clinical illnesses were due to infections and infestations (N=262, 74%) with malaria (99/262, 38%) and respiratory tract infections (84/262, 32%) being most common. Forty-seven (47%) of all enrolled participants had at least one episode of malaria. Other clinical illnesses were distributed across various body systems. Common laboratory abnormalities included neutropenia (31%), elevated alanine transferase (16%), low hemoglobin (13%) and proteinuria (12%).
In conclusion, the predominance of infectious diseases in these healthy research participants underscores the need for adequate planning to meet the diagnostic and care needs of research participants enrolled in clinical trials.